COPING MECHANISMS AND ILLNESS PERCEPTION ASSOCIATED WITH HEALTH-RELATED QUALITY OF LIFE OF PROSTATE CANCER PATIENTS IN OGUN STATE

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ABSTRACT:

Background: The second most common malignancy in men globally is prostate cancer. Moreover, one of the regions with the highest estimated death rates from prostate cancer is sub-Saharan Africa. Similarly, the leading cause of cancer-related mortality among Nigerian men is prostate cancer. However, negative illness perceptions, including worry about the disease and the severity of symptoms, have been linked to poorer prognosis among cancer patients. Generally, cancer patients adopt various coping mechanisms to deal with these stressors. Meanwhile, little is known about the health-related quality of life of prostate cancer patients in this region, regarding their coping mechanisms and illness perception. Therefore, this study examined, coping mechanisms and illness perceptions associated with health-related quality of life among prostate cancer patients in Ogun State, Nigeria.

Methods: This cross-sectional study employed the Purposive sampling technique. Correlation analysis was used to determine the association between coping mechanisms, illness perception, and the health-related quality of life of participants.

Results: The association between illness perception and health-related quality of life was positively correlated and statistically significant (r=.547, p=.000). However, in the association between coping mechanism and health-related quality of life; problem-focused coping and health-related quality of life were found to be positively correlated and statistically significant (r=.228, p=.000); emotion-focused coping and health-related quality of life were found to be positively correlated and statistically significant (r=.388, p=.000); while avoidant coping and health-related quality of life were found to be negatively correlated (r= -0.192, p=.000).

Conclusion: This study found that a higher illness perception score correlated with a higher health-related quality of life score. Also, a higher problem-focused and emotion-focused coping mechanism score correlated with a higher health-related quality of life score. While a higher avoidant coping score inversely correlated to a lower health-related quality of life score.

KEYWORDS: Coping mechanism, Health-related quality of life, Illness Perception, Prostate cancer, sub-Saharan Africa, Quality of Life.

INTRODUCTION

Background to the study

Prostate cancer (CaP) is the most prevalent cause of cancer-related death among men and the second most common malignancy in males globally (Testa et al., 2019). Meanwhile, studies have demonstrated that, when detected early, prostate cancer can be adequately treated or cured (Carlsson & Vickers, 2020). However, it has been shown that the majority of males in Sub-Saharan Africa who have CaP receive a late-stage diagnosis (Seraphin et al., 2021). Therefore, the majority of patients in this area who have prostate cancer will experience the debilitating consequences of receiving a late cancer diagnosis–when the illness must have proceeded to an advanced stage in the course of the disease's natural pathogenesis; hence making a significant impact on patients' quality of life.

Furthermore, according to empirical evidence, the Health-Related Quality of Life (HRQoL) of cancer survivors is strongly influenced by their illness perception and coping strategies (De Rooij et al., 2018), as well as the form of therapy being received (Bellardita et al., 2013). Consequently, more research is being conducted, studying patients' illness perceptions, which include both cognitive and emotional reactions to their disease, associated with both psychological and physical outcomes (Hagger & Orbell, 2003). Negative illness perceptions, including worry about the disease and the severity of symptoms, have been linked to poorer HRQoL, psychological conditions, and poor prognosis for cancer patients (Ashley et al., 2015; Traeger et al., 2009). Hence, negative illness perceptions have an impact on cancer survivors' health outcomes (including their quality of life). When cancer survivors are given clear information about their diagnosis, side effects, and prognosis, the illness perception of their sickness may become more in line with the severity or prognosis of their disease (De Rooij et al., 2018; Nicolaije et al., 2015), affecting HRQoL either directly or indirectly.

Generally, patients adopt various coping mechanisms (Problem-focused coping, Avoidant coping, and Emotion-focused coping) to deal with these stressors. According to Folkman and Moskowitz (Folkman & Moskowitz, 2004), the term *coping* describes the behavioural and cognitive techniques people employ to manage their stress.

Moreover, according to Brock (1993), the philosophical concept of quality of life is built on three fundamental tenets: (a) characteristics of a good life, (b) satisfying preferences for a good life, and (c) if one perceives one's life as good or bad based on life experiences. Additionally, the perception of one's degree of physiological and psychological well-being based on one's health or medical treatment affects one's judgment of their quality of life in relation to their health (Bellardita et al., 2013).

Considering the increase in the number of CaP survivors in the last 25 years, it is increasingly essential to assess the concerns linked to prostate cancer quality of life (DeSantis et al., 2014), such concerns also include patients' illness perception and coping strategies.

Consequently, enhancing patient quality of life is presently a top priority in cancer care. Hence, more empirical evidence from examining the dynamics between coping mechanisms, illness perception, and the health-related quality of life of prostate cancer patients in Nigeria is required, for providing accurate data to inform decision-making in providing precise cancer care and intervention, as a necessary first step to improve the health-related quality of life of

prostate cancer patients; hence, improving their experience of the medical condition. Therefore, this study was conducted to assess the health-related quality of life of prostate cancer patients concerning their coping mechanisms and illness perception. The Transactional Stress and Coping Model (TSCM) for the cancer population (Hamilton et al., 2017), was adopted to build the science describing the association between the Coping mechanism, Illness perception, and the Health-Related Quality of patients being treated for prostate cancer.

Statement of the Problem

Prostate cancer survivors can be negatively impacted by the side effects of the disease, such as bowel and bladder incontinence and sexual dysfunctions linked to its medical and surgical therapies. Studies show that a cancer diagnosis is characterized by attitudes of anxiety and fatalism among black men (Hamilton et al., 2017), these attitudes have been associated with increased negative illness perception among such population (Kazer et al., 2013).

Consequently, a variety of coping strategies are adopted by patients, as a means of dealing with the effects of their illness. QoL is affected not only by the objective medical condition and the patient's perceptions but also by their coping style (Brown et al., 2000). These coping strategies (active or avoidant coping strategies) may lead to an increase in the patient's QoL or a decrease in QoL (Guan et al., 2020).

Aim of the Study

The general objective of this study was to assess the health-related quality of life of prostate cancer patients in relation to their coping mechanisms and illness perception. As a result, providing new light on the understanding of the dynamics of patient's health-related quality of life.

This was operationalised by the following specific objectives:

1.   Assessing the association between coping mechanism and quality of life among prostate cancer patients.

2.   Assessing the association between illness perception and the quality of life of prostate cancer patients.

LITERATURE REVIEW

Epidemiological Review

An estimated 80,000 people worldwide die of prostate cancer each year, with an average of 190,000 new cases diagnosed each year (Rawla, 2019); in 2019 Sub-Saharan Africa was among the regions with the highest estimated death rate (MaryBeth, 2019).

However, the QoL of prostate cancer survivors can be negatively impacted by the physiological side effects of the disease, such as bowel and bladder incontinence and sexual dysfunctions linked to its medical and surgical therapies. Additionally, the perception of one's degree of physiological and psychological well-being based on one's health or medical treatment affects one's judgment of their quality of life in relation to their health (Bellardita et al., 2013).

Moreover, the process of prostate cancer diagnosis includes physical examination of the prostate gland called Digital Rectum Exam (DRE); a blood test called Prostate Specific Antigen test (PSA); histological examination via prostate biopsy; and Imaging via Magnetic Resonance Imaging (MRI) (Talala et al., 2020). Active surveillance, hormonal therapy, radiation therapy, surgery, chemotherapy, cryotherapy, and radical prostatectomy are the main forms of treatment for prostate cancer (Ansmann et al., 2018; Tucci et al., 2018).

Meanwhile, nonmodifiable risk factors that predispose men to prostate cancer are age, gender (male), family history of the disease, and race (Pernar et al., 2018). Consequently, the risk of having prostate cancer is higher among adult males; however, men of African ancestry are at higher risk of the disease from an earlier age (40 years) compared to men of European ancestry, who are at higher risk from a later age (50 years) (Badal et al., 2020); with the disease being more aggressive among men of African ancestry (Badal et al., 2020; Cronin et al., 2018). Therefore, the burden of the disease is greater among men of African ancestry. On the other hand, modifiable risk factors for prostate cancer include cigarette smoking, unhealthy diets, unhealthy use of alcohol and tobacco use (Pernar et al., 2018).

Considering the increase in the number of CaP survivors in the last 25 years, it is increasingly essential to assess the concerns linked to prostate cancer quality of life (DeSantis et al., 2014), such concerns also include patients' coping strategies and illness perception.

THEORETICAL REVIEW

From the WHO definition of Quality of Life ("an individual's perception of their position in life in the context of the culture and value systems in which they live and concerning their goals, expectations, standards, and concerns" (WHOQOL, 1995, p. 1403), it can be inferred that quality of life is a function of an individual's *perception*. Moreover, empirical evidence has linked negative illness perceptions, including worry about the disease and the severity of symptoms, have been linked to poorer Health-Related Quality of Life (HRQoL), psychological conditions and poor prognosis for cancer patients (Ashley et al., 2015; Traeger et al., 2009). In addition, patients adopt various coping mechanisms to deal with these stressors.

Furthermore, the quality of life of cancer survivors has been strongly linked to their illness perception and coping strategies (De Rooij et al., 2018). According to Folkman and Moskowitz (2014), the term *coping* describes the behavioural and cognitive techniques people employ to manage their stress.

Consequently, this study adopted the Transactional Stress and Coping Model (TSCM) for the cancer population (Lazarus and Folkman, 1984) to build the science describing the association between coping mechanisms, illness perception, and the Health-Related Quality (HRQoL) of patients being treated for prostate cancer in Nigeria.

The model is comprised of three (3) major variables:

1.   **Explanatory variables**: this includes individual resilience, conceptualised as internal resources; social support and financial resources conceptualized as external resources.

2.   **Mediating factors**: this includes Appraisal of illness (illness perception) and coping.

Patients and families who are dealing with a serious illness employ a variety of coping mechanisms as part of a dynamic process that both influences and affects their environment, resources, and mental well-being (Greer et al., 2022).

The Transactional Stress and Coping Model (Folkman, 2004; Lazarus & Folkman, 1984) indicates that the two prototypical states of challenge and threat are the result of cognitive assessments of a situation's implication and a person's capacity to respond to it.

In the Transactional Stress and Coping Model (TSCM), a primary appraisal is the assessment of whether a circumstance is neutral or stressful. Neutral circumstances are thought to require no instrumental action by the individual in question, to ensure a good result, whereas it is supposed that stressful circumstances call for particular action(s). Stressful circumstances are categorised into two groups and can be challenging or threatening. Circumstances that are perceived to present opportunities for development, a successful outcome, and gain are considered challenging (e.g., positive health outcome). Threatening circumstances are those that are perceived to have the ability to cause damage or loss (e.g., negative health outcome).

The perception of challenge or threat is established in the secondary appraisal of one's capacity to cope and react to stressful circumstances.

The Transactional Stress and Coping Model (TSCM), postulated by Lazarus and Folkman (1984), states that the exchanges (or interactions) that take place between an individual and their environment have an impact on that individual's ability to cope with and adapt to difficulties and problems.

According to Folkman and Greer (2000), coping is assessed by three (III) overarching coping strategies indicating the degree to which the respondent has been engaging in that coping strategy:

I. Problem-Focused Coping.

Characterized by the elements of constructive reframing, planning, active coping, and using informational assistance. A high level denotes the use of coping mechanisms intended to alter the stressful circumstance. High scores are a sign of resilience, psychological toughness, and a hands-on approach to problem-solving, and they also portend good things to come.

II. Emotion-Focused Coping.

Typified by the traits of humour, self-blame, acceptance, venting, and using emotional support. A high level denotes the use of coping mechanisms intended to control feelings brought on by stressful circumstances. Although high or low levels are not always linked to psychological well-being, they can be utilised to help formulate the respondent's coping mechanisms more comprehensively.

III. Avoidant Coping.

Characterised by denial, substance abuse, behavioural disengagement, and self-distraction. A high level denotes attempts, either mental or physical, to detach from the stressor. Adaptive coping is usually indicated at lower levels.

3.   **Outcome Factor**: This is the patients' Quality of Life (QoL) comprising physical health, emotional well-being, social functioning, and spiritual/existential well-being.

EMPIRICAL REVIEW

Guan et al., (2020) conducted a study which emphasized the significance of evaluating patients' coping mechanisms, due to their substantial influence on patients' quality of life; in that research study, it was discovered that after controlling for individual characteristics, symptoms, and the degree of illness uncertainty, avoidant coping mechanisms had a negative relationship with mental quality of life, while active coping mechanisms had a positive relationship with mental quality of life with avoidant coping mechanisms showing a greater relationship with quality of life than active coping mechanisms (Guan et al., 2020).

On the other hand, negative illness perceptions, including worry about the disease and the severity of symptoms, have also been linked to poorer HRQoL, psychological conditions and poor prognosis for cancer patients (Ashley et al., 2015; Traeger et al., 2009). From data collected from 2457 cancer survivors, it was concluded that positive illness perceptions are associated with better HRQoL and survival; in that study, it was found that cancer survivors with negative illness perceptions appear to have the most adverse outcomes (De Rooij et al., 2018).

However, more investigation conducted using a public health theoretical approach is required to understand the dynamics between coping mechanisms and illness perception and the health-related quality of life (QoL) of prostate cancer patients in Nigeria; providing more light on the development of precise cancer care and intervention to improve quality of life among this population. Hence, this study was conducted to fill this important gap.

CONCEPTUAL FRAMEWORK

The Transactional Stress and Coping Model for the cancer population (Lazarus and Folkman, 1984) was employed to conceptualise the conceptual framework adopted for this study. The model has three key components: (I) explanatory variables, (II) mediator variables and (III) outcome factors.

Explanatory variables contain resilience conceptualised as internal resources; social support and financial resources conceptualized as external resources.

The mediating variables are conceptualized as coping mechanisms and illness perception.

The only outcome variable is quality of life, on four levels: physical health, emotional well-being, social functioning, and spiritual/existential well-being (see Figure 1).
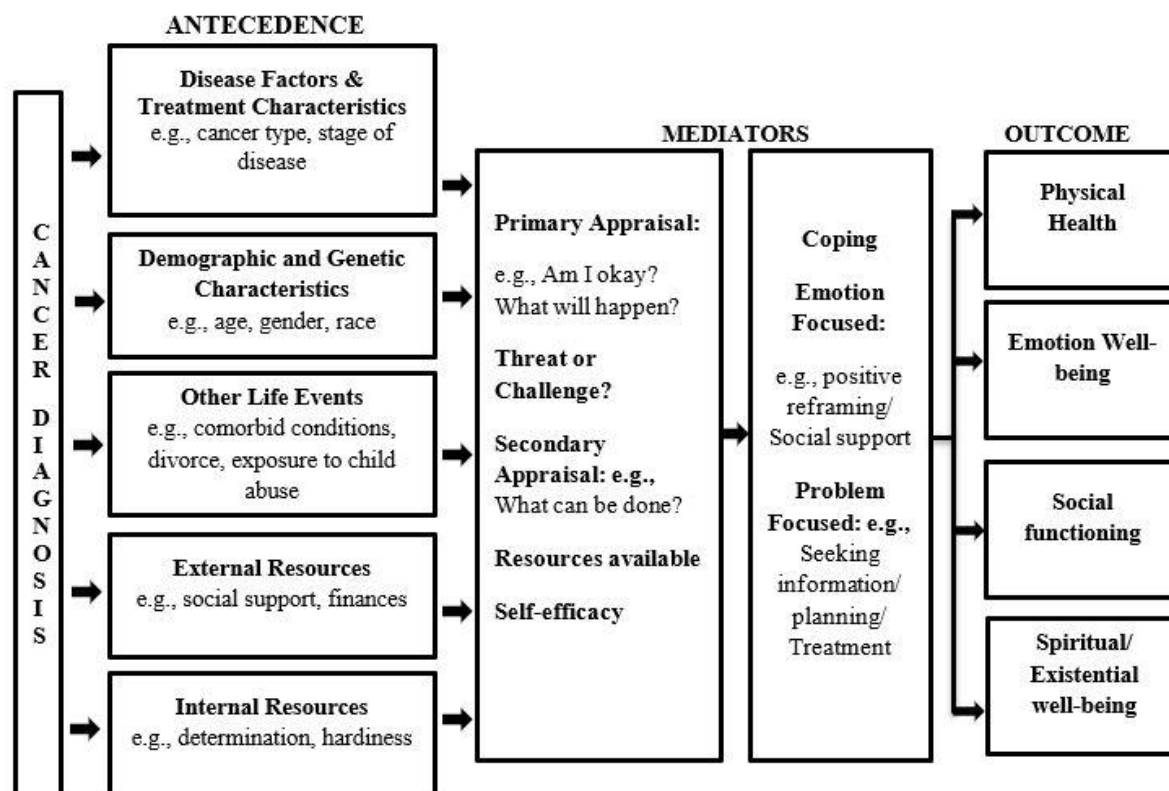
Figure 1: *Transactional Stress and Coping Model Conceptual Framework*

Note: Conceptual Framework of Transactional Stress and Coping Model for cancer population. From Stress, Appraisal and Coping, by Lazarus R. S. and Folkman S., 1984, *New York: Springer.*

METHODOLOGY

Study Design

The cross-sectional survey design was utilized in this study to elucidate the problem phenomenon

Study Area

This study was conducted among the prostate cancer community in Ogun state, Southwestern Nigeria. The study population comprised histologically diagnosed prostate cancer patients above 40 years of age. Two tertiary hospitals within Ogun State were selected as study areas for this study; Federal Medical Centre, Abeokuta (FMCA) and Babcock University Teaching Hospital (BUTH), respectively located in Abeokuta south local government area and Ikenne local government area, Ogun State, Nigeria.

Sample size and sampling Technique

Purposive sampling technique was employed in selecting participants who were eligible for this study. Eligible participants included histologically diagnosed prostate cancer patients, aged 40 years and above, who gave their informed consent to voluntarily participate in the study.

The computed sample size for this study was 384. At the end of data collection, 387 participants were recruited with questionnaires completed.

Instrumentation

The instruments for data collection for this study were adopted, purposely, to precisely measure each study variable. The instruments that were used in addressing the variables within each component are presented below:

I.   **Explanatory variables**.

Demographic and genetic characteristics: age, marital status, ethnic group.

External resource: this was conceptualised as social support and financial toxicity and was assessed using the Multidimensional Scale of Perceived Social Support (MSPSS) by Zimet et al. (1988) and the Comprehensive Score for Financial Toxicity (COST) by De Souza et al. (2014) respectively.

Internal resources: conceptualised as resilience/hardiness, were assessed using the Brief resilience scale by Smith et al. (2008).

II.   **Mediator variables**.

Illness perception: this was assessed using The Brief Illness Perception Questionnaire by Broadbent et al., 2006.

Coping mechanism: this was assessed using the Brief COPE by Carver (1997).

III.   **Outcome variable**.

Health-related quality of life, the outcome variable was assessed using the Functional Assessment of Cancer Therapy – Prostate instrument (FACT-P) by Esper et al., (1997).

Reliability of Instrument

Cronbach's alpha internal consistency analysis of the test was used to test the reliability of each variable and its instrument. The internal resource was measured using the Brief resilience scale (BRS), of which Cronbach's alpha analysis of the test of reliability for this was .970. External resources were measured using the Multidimensional Scale of Perceived Social Support (MSPSS) and Comprehensive Score for financial Toxicity (COST); the result of the Cronbach's alpha analysis of the test of reliability for these was a good score of .930 and .917 respectively. Mediating variables assessed information on coping mechanisms and illness perception, measured using the Brief Illness Perception Questionnaire and the Brief COPE; these had a Cronbach's alpha test of reliability score of .721 and .828 respectively. The outcome variable assessed information on the patient's quality of life; this was measured using the FACT-P, and the result of Cronbach's alpha analysis for the test of reliability for this was a good score of .909.

Validity of Instrument

Standardized instruments was utilised in this investigation, which has been proven to be appropriate for the study population after being employed and validated in other studies (Dar

et al., 2021; Yusoff et al., 2010; Sánchez et al., 2021). Construct validity and face validity were conducted for these psychometrically sound instruments, in this study.

Method of Collection and Data Analysis

Study data was collected using a paper and pencil questionnaire. Data collected was analysed using IBM SPSS version 26. Correlation analysis was used in determining the association between illness perception and health-related quality of life and the association between coping mechanisms and health-related quality of life.

Ethical considerations

Ethical approval was obtained from the Institutional Review Board of the Federal Medical Centre, Abeokuta Health Research Ethics Committee (HREC). Informed consent was also obtained from all eligible participants before they were recruited for the study.

RESULTS

Data was collected from 387 participants: 288 (74.4% of the total) from FMCA and 99 from BUTH, accounting for 25.6% of the total study population. Among the study participants, 4.4% were between the ages of 40-49 years, 18.3% were between 50-59 years, 34.6% were between 60-69 years, and 27.1% were between 70-79 years, 14.7 were between 80-89 and 0.8% were between 90-99 years of age. The major ethnic group was Yoruba (68.2%), while 9.6% of the population were Ibo, followed by Hausa (8.8%) and 13.4% for other ethnicities. Relationship status showed that 92.8% were married, 4.9% were widowed, and 2.3% were divorced/separated (see Table 1).

Table 1: Demographic Characteristics of the respondents

Demographic Variables	Respondents in this study N = 387	
	Frequency (n)	Percentage (%)
Facility		
FMCA	288	74.4
BUTH	99	25.6
Age in Years		
40-49	17	4.4
50-59	71	18.3
60-69	134	34.6
70-79	105	27.1
80-89	57	14.7

90-99	3	0.8	

Relationship Status

Married	359	92.8
Divorced/Separated	9	2.3
Widowed	19	4.9

Ethnicity

Yoruba	264	68.2
Hausa	34	8.8
Ibo	37	9.6
Others	52	13.4

Association between Illness Perception and Health-related Quality of Life

In assessing the association between Illness Perception (IP) and Health-Related Quality of Life (HRQoL), Pearson Correlation analysis was performed. Pearson product correlation of IP and HRQoL was .547, with a .000 statistically significant level (r = .547, p = < .001), (see table 2).

Association between Coping mechanism and Health-related Quality of Life

Similarly, in assessing the association between Coping Mechanism (CM) and HRQoL, Pearson Correlation analysis was also performed. Pearson product correlation of CM and HRQoL was .186, with a .000 statistically significant level (r = .186, p = < .001), (see table 2).

Table 2: Pearson Correlation showing the association between Illness Perception, Coping Mechanism, and Health-Related Quality of Life (HRQoL)

		Illness Perception	Cope Mechanism
HRQoL	Pearson Correlation	.547[**]	.186[**]
Measured on a	Sig. (2-tailed)	.000	.000

156-point scale	N		387	387

**. Correlation is significant at the 0.01 level (2-tailed).

Moreover, to further elucidate the association between coping mechanisms and the quality of life of prostate cancer patients. Pearson Correlation analysis was conducted to assess the association between health-related quality of life and the three (3) aspects of Coping (Problem-focused coping, Emotion-focused coping, and Avoidant coping), (see Table 3).

Pearson product correlation of Problem-focused coping and HRQoL was .228 (r = .228, p = 0.000).

While Pearson product correlation of Emotion-focused coping and HRQoL was .338 (r = .338, p = 0.000).

However, Pearson product correlation for Avoidant coping mechanism and HRQoL was -0.192 (r = -0.192, p = 0.000).

Table 3: Pearson Correlation showing association between Health-Related Quality of Life (HRQoL) and the three (3) aspects of Coping

		Problem Focused Coping	Emotional Focus Coping	Avoidant Coping
HRQoL	Pearson Correlation	.288[**]	.388[**]	-0.192[**]
measured on a	Sig. (2-tailed)	.000	.000	.000
156-point scale	N	387	387	387

**. Correlation is significant at the 0.01 level (2-tailed).

DISCUSSION

Firstly, Pearson Correlation analysis was performed to assess the association between Illness Perception (IP) and Health-Related Quality of Life (HRQoL). Pearson product correlation of illness perception and health-related quality of life was found to be positive and statistically significant (r = .547, p = < .001). Hence, a higher illness perception score correlated with a higher health-related quality of life score among prostate cancer patients. This is in line with the findings of De Rooij et al., 2018, in their study data was collected from 2457 cancer survivors; from their findings, the researcher concluded that positive illness perceptions are associated with better HRQoL and survival; in that study, it was found that cancer survivors with negative illness perceptions appear to have the most adverse outcomes.

Secondly, analysis was conducted on the different aspects of coping mechanisms (Problem-focused coping, Avoidant coping, and Emotion-focused coping), using Pearson Correlation analysis, to ascertain their association with patients' Health-Related Quality of Life. From the result, it was found that the correlation between Problem-focused coping and HRQoL was positive and statistically significant ($r = .338$, $p = < .001$). Hence, a higher problem-focused coping score correlated with a higher health-related quality of life score among prostate cancer patients. Furthermore, the Pearson product correlation of Emotion-focused coping and Health-related quality of life was found to be positive and statistically significant ($r = .228$, $p = < .001$). Hence, a higher emotion-focused score correlated with a higher health-related quality of life score among prostate cancer patients.

Meanwhile, the correlation between avoidant coping and HRQoL was found to be negatively correlated and statistically significant ($r = -0.192$, $p = < .001$). Hence, the negative correlation indicates that a higher avoidant coping score was inversely correlated to a lower health-related quality of life score among prostate cancer patients. These results also support existing evidence from a study conducted recently by Guan et al., (2020), which emphasized the significance of evaluating patients' coping mechanisms, due to their substantial influence on patients' quality of life; in that research study, it was discovered that avoidant coping mechanisms had a negative relationship with mental quality of life, while active coping mechanisms (problem-focused coping) had a positive relationship with mental quality of life. Therefore, our findings further validate and emphasize the significance of evaluating patients' coping mechanisms in association with their health-related quality of life.

CONCLUSION

This study found that illness perception is positively associated with patients' health-related quality of life; problem-focused, and emotion-focused coping was also positively associated with HRQoL, while avoidant coping is negatively associated with patients' HRQoL. Therefore, a higher illness perception score correlated with a higher health-related quality of life score. Also, a higher problem-focused and emotion-focused coping mechanism score, correlated with a higher health-related quality of life score. While a higher avoidant coping score inversely correlates to a lower health-related quality of life score.

RECOMMENDATION

This study used the cross-sectional study design in elucidating the problem phenomenon; therefore, a cause-and-effect relationship could not be established. Hence, further research studies using experimental design or longitudinal studies are required to establish a cause-and-effect relationship among study variables.

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Appendix A: Ethical Approval

FEDERAL MEDICAL CENTRE

Olabisi Onabanjo Way, Idi-Aba, Abeokuta, Ogun State, Nigeria
08033765192, 08095948005-7, 08095947660
E-mail: md_officefmcabk@yahoo.com
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PROF. ABDUS SAMIU A. MUSA-OLOMU	DR. ADEKUNLE S. ADEDIRAN	MR. A. O. VAUGHAN
Medical Director	Head of Clinical Services	Director of Administration &
MBBS, FWACS, FICS, Msc., Phd	MBBS (Ib), MWACP, MRCPCH, FMCPaed, FIPNA	Secretary to the Board of Management
		B.Ed (Eng) Cert, Health Planning & Mgt. MPA; AHAN

05 JUL 2023
APPROVED

5th July, 2023

FMCA/470/

NAME OF PRINCIPAL INVESTIGATOR: OLORUNNIYI SHOLA BLESSING

TITLE OF STUDY: ILLNESS PERCEPTION AND COPING MECHANISM ASSOCIATED WITH HEALTH-RELATED QUALITY OF LIFE AMONG PROSTATE CANCER PATIENTS RECEIVING CARE IN TERTIARY HOSPITALS, OGUN STATE

RESEARCH LOCATION:　　　　FEDERAL MEDICAL CENTRE, ABEOKUTA

PROTOCOL NUMBER:　　　　FMCA/470/HREC/01/2023/11
NREC ASSIGNED NUMBER:　　NHREC/08/10-2015
FEDERAL WIDE ASSURANCE:　U.S/REG NO: FWA/Q0018660/05/28/2017
DATE OF RECEIPT OF VALID APPLICATION: 8th March, 2023

NOTIFICATION OF EXECUTIVE APPROVAL OF PROTOCOL

This is to inform you that the Federal Medical Centre, Abeokuta Health Research Ethics Committee (HREC) has decided to give Executive approval to your Research proposal, after necessary reviews and corrections, under the regulation guiding experiment in human subjects.

This approval is for a Period of one year from 5th July, 2023 to 4th July, 2024. If there is delay in starting this research, please inform the HREC so that dates of approval can be adjusted accordingly. Note that no activity related to this research may be conducted outside these dates. No changes are permitted in the research without prior approval by HREC.

All forms and questionnaires used in this study must carry the HREC assigned number and the duration of HREC Approval.

You are to note further that, the National Code of Health Research Ethics requires you to comply with all institutional guidelines, rules and regulation of the codes. Please ensure that any adverse effect from your study is promptly reported to the HREC Federal Medical Centre, Abeokuta.

You are expected to submit a report to this Committee every three (3) months from the date of approval. The HREC reserves the right to conduct compliance visits on your research sites without pervious notification.

Thank you.

J.A. ADETUMERUN
For Chairman, Health Research Ethics Committee

Correspondence to the Office of the Medical Director